General

Guideline Title

Uterine septum: a guideline.

Bibliographic Source(s)

Practice Committee of the American Society for Reproductive Medicine. Uterine septum: a guideline. Fertil Steril. 2016 Sep 1;106(3):530-40. [59 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the level of evidence (Level I-III) and the strength of the evidence (Grade A-C) are given at the end of the "Major Recommendations" field.

Diagnosis of Septate Uterus

Summary Statements

- There is fair evidence that 3-D ultrasound, sonohysterography, and magnetic resonance imaging (MRI) are good diagnostic tests for distinguishing a septate and bicornuate uterus when compared with laparoscopy/hysteroscopy. (Grade B)
- It is recommended that imaging with hysteroscopy should be used to diagnose uterine septa rather than laparoscopy with hysteroscopy because this approach is less invasive (Grade B).

Limitations of the Literature

Summary Statement

- The data regarding reproductive implications of septate uteri and treatment effects are limited and comprised primarily of observational, principally descriptive studies without untreated control groups.

Does a Septum Impact Fertility?

Summary Statement

- There is insufficient evidence to conclude that a uterine septum is associated with infertility. (Grade C)

Does Treating a Septum Improve Fertility in Infertile Women?

Summary Statement

- Several observational studies indicate that hysteroscopic septum incision is associated with improved clinical pregnancy rates in women with infertility. (Grade C)

Does a Septum Contribute to Pregnancy Loss or Adverse Pregnancy Outcome?

Summary Statements

- There is fair evidence that a uterine septum contributes to miscarriage and preterm birth. (Grade B)
- Some evidence suggests that a uterine septum may increase the risk of other adverse pregnancy outcomes such as malpresentation, intrauterine growth restriction, placental abruption, and perinatal mortality. (Grade B)

Does Treating a Septum Improve Obstetrical Outcomes?

Summary Statements

- Some limited studies indicate that hysteroscopic septum incision is associated with a reduction in subsequent miscarriage rates and improvement in live-birth rates in patients with a history of recurrent pregnancy loss. (Grade C)
- Some limited studies indicate that hysteroscopic septum incision is associated with an improvement in live-birth rate in women with infertility or prior pregnancy loss. (Grade C)

Are Septum Characteristics Associated with Worse Reproductive Outcomes?

Summary Statement

- There is insufficient evidence to conclude that obstetric outcomes are different when comparing the size as defined by length or width of uterine septa. (Grade C)

Surgery to Treat a Uterine Septum

Summary Statement

- There is insufficient evidence to recommend a specific method for hysteroscopic septum incision. (Grade C)

How Long After Surgical Treatment of a Uterine Septum Should a Woman Wait to Conceive?

Summary Statement

- Although the available evidence suggests that the uterine cavity is healed by 2 months postoperatively, there is insufficient evidence to advocate a specific length of time before a woman should conceive. (Grade C)

Should Preoperative Management to Thin the Endometrium Be Used?

Summary Statement

- There is insufficient evidence for or against recommending danazol or gonadotropin-releasing hormone (GnRH) agonists to thin the endometrium prior to hysteroscopic septum incision. (Grade C)

Is Adhesion Prevention Needed?

Summary Statement

- There is insufficient evidence to recommend for or against adhesion prevention treatment, or any specific method following hysteroscopic septum incision. (Grade C)

Recommendations

- It is recommended that imaging or imaging with hysteroscopy should be used to diagnose uterine septa rather than laparoscopy with

hysteroscopy because this approach is less invasive. (Grade B)
- In a patient with infertility, prior pregnancy loss, or poor obstetrical outcome it is reasonable to consider septum incision. (Grade C)
- In a patient without infertility or prior pregnancy loss, it may be reasonable to consider septum incision following counseling regarding potential risks and benefits of the procedure. (Grade C)

Definitions

Level of Evidence

Level I: Evidence obtained from at least one properly designed randomized, controlled trial.

Level II-1: Evidence obtained from well-designed controlled trials without randomization.

Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.

Level III: Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.

Strength of Evidence

Grade A: There is good evidence to support the recommendations, either for or against.

Grade B: There is fair evidence to support the recommendations, either for or against.

Grade C: There is insufficient evidence to support the recommendations, either for or against.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Septate uterus
- Infertility
- Pregnancy loss

Guideline Category

Diagnosis

Management

Treatment

Clinical Specialty

Obstetrics and Gynecology

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To review the literature regarding septate uterus and determine optimal indications and methods of treatment for it

Target Population

Women with a septate uterus

Interventions and Practices Considered

Diagnosis/Evaluation

1. 3-D ultrasound
2. Sonohysterography
3. Magnetic resonance imaging (MRI)
4. Imaging with hysteroscopy

Treatment/Management

1. Hysteroscopic septum incision
2. Counseling regarding potential risks and benefits of septum incision

Note: The following interventions/practices were considered but there was insufficient evidence to make recommendations for or against: comparing the size (i.e., length or width) of uterine septa to determine obstetric outcomes; specific methods for hysteroscopic septum incision; specific lengths of time before a woman should conceive after septum incision; use of danazol or gonadotropin-releasing hormone (GnRH) agonists to thin the endometrium prior to hysteroscopic septum incision; adhesion prevention treatment; or any specific method following hysteroscopic septum incision.

Major Outcomes Considered

- Pregnancy rate
- Implantation rate
- Live-birth rate
- Miscarriage rate
- Risk of infertility
- Adverse pregnancy outcomes

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Description of Search

This clinical practice guideline was based on a systematic review of the literature. Systematic literature searches of relevant articles were performed in the electronic database MEDLINE through PubMed in March and April 2015, with a filter for human subject research. No limit or filter was used for time period covered or English language, but articles were subsequently culled for English language.

A combination of the following medical subject headings or text words/keywords were used: abortion, adhesion, adhesions, arcuate, bicornuate, birth control pill, congenital anomalies, congenital anomaly, congenital abnormalities, congenital abnormality, contraceptive, danazol, detection, diagnose, diagnosis, hysterosalpingogram, hysteroscopic, hysteroscopy, infertility, intrauterine, laparoscopic, laparoscopy, live birth, Lupron, metroplasty, miscarriage, magnetic resonance imaging (MRI), outcome, perinatal outcome, perinatal outcomes, pregnancies, pregnancy, pregnancy loss, premature, preterm, progestin, repair, resection, resectoscope, septa, septal, septate, septum, sonohysterogram, surgery, treatment, ultrasonography, uteri, uterine, uterus.

Initially, titles and abstracts of potentially relevant articles were screened and reviewed for inclusion/exclusion criteria. Protocols and results of the studies were examined according to specific inclusion criteria. Only studies that met the inclusion criteria were assessed in the final analysis. Studies were eligible if they met one of the following criteria: primary evidence (clinical trials) that assessed the effectiveness of a procedure correlated with an outcome measure (pregnancy, implantation, or live-birth rates); meta-analyses; and relevant articles from bibliographies of identified articles.

Four members of an independent task force reviewed the full articles of all citations that possibly matched the predefined selection criteria. Final inclusion or exclusion decisions were made on examination of the articles in full. Disagreements about inclusion among reviewers were discussed and solved by consensus or arbitration after consultation with an independent reviewer/epidemiologist.

Summary of Inclusion/Exclusion Criteria

Inclusion Criteria

- Level 1, II-1, II-2, II-3 studies; systematic reviews/meta-analyses
- Human studies
- English
- Studies that report clinical (fertility and/or obstetrical) outcomes
- Studies that focus on septate, arcuate, bicornuate uterine anomalies and/or adhesions

Exclusion Criteria

- Level III studies: small series, case reports, reviews, opinions, off topic
- Animal studies
- Non-English
- Studies that focus on prevalence with no fertility and/or obstetrical outcome measures
- Studies that do not focus on septate uterus, but focus on unicornuate or didelphic uteri, or fibroids and polyps, or cervix and vagina, obstructed hemivagina and ipsilateral renal anomaly (OHVIRA) or Herlyn-Werner-Wunderlich (HWW), Asherman, Fryns, or Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome
- Studies with a focus on amenorrhea, blood flow, cancer, dysmenorrhea, endometriosis, hemodynamics, menorrhagia, ovarian maldescent, polycystic ovary syndrome, surgical technique only, uterine horn, uterine prolapse, vascular endothelial growth factor (VEGF)
- Studies with a focus on pediatric or postpartum population
- Studies with a focus on abdominal metroplasty

Number of Source Documents

Number of studies identified in an electronic search and from examination of reference lists from primary and review articles = 1,034; number of studies included = 204.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Level of Evidence

Level I: Evidence obtained from at least one properly designed randomized, controlled trial.

Level II-1: Evidence obtained from well-designed controlled trials without randomization.

Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.

Level III: Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The quality of the evidence was evaluated using the grading system found in the "Rating Scheme for the Strength of the Evidence" field and is assigned for each reference in the bibliography of the original guideline document.

Systematic reviews/meta-analyses were individually considered and included if they followed a strict methodological process and assessed relevant evidence.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The literature was reviewed to answer the following questions:

1. Does a septum cause infertility?
2. Does a septum contribute to adverse obstetrical outcomes? Adverse obstetrical outcomes are pregnancy loss (early and late), preterm birth, and intrauterine death.
3. Does treating a septum improve fertility? What method or technique improves outcomes?
4. Does treating a septum improve obstetrical outcomes? (pregnancy loss, duration of pregnancy, rupture)
5. How to diagnose a septum? Are there other methods as accurate as laparoscopy/hysteroscopy to diagnose a septum?
6. Are some types of deformity associated with worse outcomes? (short/long; thin/thick)
7. How long after septum repair should a woman wait to conceive?
8. Should you give preoperative management (medications vs. nothing) to thin the endometrium? (danazol, Lupron, birth control pill, progestins)
9. Does adhesion prevention work? (treatment vs. nothing, estrogen therapy, Foley balloon, intrauterine device [IUD], barrier slurries)

Rating Scheme for the Strength of the Recommendations

Strength of Evidence

Grade A: There is good evidence to support the recommendations, either for or against.

Grade B: There is fair evidence to support the recommendations, either for or against.

Grade C: There is insufficient evidence to support the recommendations, either for or against.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This document was reviewed by American Society for Reproductive Medicine members, and their input was considered in the preparation of the final document.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- There is fair evidence that 3-D ultrasound, sonohysterography, and magnetic resonance imaging (MRI) are good diagnostic tests for distinguishing a septate and bicornuate uterus when compared with laparoscopy/hysteroscopy.
- Several studies indicate that treating a uterine septum is associated with an improvement in live-birth rates in women with a history of prior pregnancy loss, recurrent pregnancy loss, or infertility.

Potential Harms

There have been 18 case reports in the literature of uterine rupture during pregnancy or delivery following septum incision. Risk of subsequent pregnancy-related uterine rupture is correlated with excessive septal excision, penetration of the myometrium, uterine wall perforation, and excessive use of cautery or laser energy during the initial septum incision procedure.

Qualifying Statements

Qualifying Statements

This report was developed under the direction of the Practice Committee of the American Society for Reproductive Medicine as a service to its members and other practicing clinicians. Although this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs of the individual patient, available resources, and institutional or clinical practice limitations. The Practice Committee and the Board of Directors of the American Society for Reproductive Medicine have approved this report.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Sep 1

Guideline Developer(s)

American Society for Reproductive Medicine - Nonprofit Organization

Source(s) of Funding

American Society for Reproductive Medicine

Guideline Committee

Practice Committee of the American Society for Reproductive Medicine

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Financial Disclosures/Conflicts of Interest

All Committee members disclosed commercial and financial relationships with manufacturers or distributors of goods or services used to treat patients. Members of the Committee who were found to have conflicts of interest based on the relationships disclosed did not participate in the discussion or development of this document.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Fertility and Sterility Web site.

Availability of Companion Documents

Continuing medical education (CME) credit related to this guideline is available from the American Society for Reproductive Medicine Web site.

Patient Resources

None provided

NGC Status

This NGC summary was completed by ECRI Institute on March 3, 2017. The information was not verified by the guideline developer.

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